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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,673	07/20/2000	BRUCE PAUL DAGGY	C75087	9337

7590 06/17/2004  
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EXAMINER

HOLLERAN, ANNE L

ART UNIT PAPER NUMBER

1642

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/600,673	<b>Applicant(s)</b> DAGGY ET AL.	
	<b>Examiner</b> Anne Holleran	<b>Art Unit</b> 1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. The amendment filed August 8, 2003 is acknowledged. Claims 1-18 were canceled. Claims 19-34 were added.

Claims 19-34 are pending and examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections Withdrawn:***

3. The rejection of claims 1 and 10 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of the amendment.
4. The rejection of claims 1-3, 5-12 and 14-18 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods where the combination of fibers includes the addition of wheat bran to cellulose, does not reasonably provide enablement for methods where the combination of fibers lacks wheat bran is withdrawn in view of the amendment.

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5. The rejection of claims 1, 2, 5, 6, 8 and 9 under 35 U.S.C. 102(e) as being anticipated by Annison et al (U.S. Patent 5,840,860; issued 11/24/1998; effective filing date for 102(e) 9/5/1996) is withdrawn in view of the amendment removing to generic “derivatives of cellulose”.

***Claim Rejections Maintained:***

6. Claims 19-21, 25-29, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Folino et al (Folino, M. et al, J. Nutr. 125: 1521-1528, 1995).

The claimed methods read on methods comprising the administration of methylcellulose to a mammal.

Folino teaches a method of administering methylcellulose to rats (see page 1522, 1<sup>st</sup> column, and Table I, page 1523). Folino teaches that the methylcellulose accounted for 1 gm of the total fiber (see Table 1). The methylcellulose appears to be administered in the form of a suspension (see notes of Table 1). Thus, Folino teaches a method that is the same as that claimed.

7. Claims 19-21, 25-29, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Folino et al (supra) in view of Cohen et al (Cohen, L.A. et al., J. Natl. Cancer Inst., 88(13): 899-907, 1996; cited in the IDS).

The claimed methods read on methods comprising the administration of methylcellulose to a human.

Folino teaches a method of administering methylcellulose to rats (see page 1522, 1<sup>st</sup> column, and Table I, page 1523). Folino teaches that the methylcellulose accounted for 1 gm of

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the total fiber (see Table 1). The methylcellulose appears to be administered in the form of a suspension (see notes of Table 1). Folino fails to explicitly teach a method comprising the administration of methylcellulose to humans for the purpose of reducing the incidence of colorectal cancer or of breast cancer.

However, Cohen teaches generally that the incidence of either breast cancer or colorectal cancer is reduced by the ingestion of dietary fibers. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the method of Folino for the treatment of humans, there being no evidence of record that the rat model is not applicable to humans.

8. Claims 19-21 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Folino et al (supra) in view of either Cohen et al (Cohen, L.A. et al., J. Natl. Cancer Inst., 88(13): 899-907, 1996; cited in the IDS) or Alabaster et al (Alabaster, O. et al., Cancer Letters, 75: 53-58, 1993; cited in the IDS) is maintained for the reasons of record.

The claimed methods read on methods comprising the administration of methylcellulose in combination with wheat bran.

Folino teaches as described above. Folino fails to teach combining methylcellulose with wheat bran. However either Cohen or Alabaster demonstrate that it is known in the art to combine soluble and insoluble fibers, and that such combinations have a synergistic effect in colon or breast cancer risk reduction.

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***New Grounds of Rejection:***

9. Claims 19-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is indefinite because the phrase “said mammal” lacks antecedent basis.

Claims 19 and 27 are indefinite because of the phrase “reducing the incidence of colorectal cancers [*or breast cancers*] in a human in need thereof”. This phrase is indefinite because the specification does not provide a definition of what constitutes a reduction in incidence of cancer, i.e. how is the reduction measured and over what time period does the reduction occur? The phrase is also indefinite because the specification does not provide a definition of “humans in need” of the method, is this any person, or just persons who are recovering from cancer and want to avoid a relapse, or is this a person with a genetic predisposition to cancer? Also, it is not clear how one would know that a reduction in cancer incidence has occurred.

10. Claims 19-22, and 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Shah (Shah et al, U.S. Patent 4,671,823; issued 06/09/1987).

The claimed methods read on methods comprising the administration of methylcellulose to a human.

Shah teaches sucrose encrusted methylcellulose particles useful as laxatives. Thus, Shah teaches a method comprising the administration of methylcellulose in combination with a sugar. The claimed methods comprise the active step of administering methylcellulose and are

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anticipated by Shah because the administration of Shah's composition would inherently result in prevention of colorectal or breast cancer. It is not necessary for Shah to have recognized this effect of methylcellulose.

11. Claims 19-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Dressman (Dressman et al, U.S. Patent 5,789,393 issued 08/04/1998; effective filing date 02/21/1992).

Dressman teaches pharmaceutical dosages of compositions comprising methylcellulose that are useful for administration to humans for the reduction of serum lipid levels and or attenuation of postprandial rise in blood glucose levels. Therefore, Dressman teaches methods comprising the administration to humans of compositions comprising methylcellulose, which is an active step that is the same as the active step of the claimed methods. Dressman teaches administration of 10g/day, 20g/day and 30gm/day (col. 31, lines 32-41). Dressman teaches a methylcellose composition that comprises a sugar (col. 15, lines 32-35), that comprises gelatin (col. 13, lines 59-60) and wherein the composition is administered as a rapidly disintegrating tablet (col. 15, lines 35-36). Therefore, Dressaman teaches methods that are the same as that claimed.

12. Claims 19-23, 25-31, 33 and 34 are rejected under 35 U.S.C. 103(a) as being anticipated by Dressman (Dressman et al, U.S. Patent 5,789,393 issued 08/04/1998; effective filing date 02/21/1992) in view of Durlach (U.S. Patent 4,232,054, issued 11/4/1980).

The claimed methods read on methods comprising the administration of methylcellulose in combination with wheat bran.

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Dressman teaches pharmaceutical dosages of compositions comprising methylcellulose that are useful for administration to humans for the reduction of serum lipid levels and or attenuation of postprandial rise in blood glucose levels. Therefore, Dressman teaches methods comprising the administration to humans of compositions comprising methylcellulose, which is an active step that is the same as the active step of the claimed methods. Dressman teaches administration of 10g/day, 20g/day and 30gm/day (col. 31, lines 32-41). Dressman teaches a methylcellulose composition that comprises a sugar (col. 15, lines 32-35), that comprises gelatin (col. 13, lines 59-60) and wherein the composition is administered as a rapidly disintegrating tablet (col. 15, lines 35-36).

Dressman fails to teach methods comprising the administration of a combination of methylcellulose and wheat bran. However, Durlach teaches that a wheat bran composition associated to a metallic proteinate such as calcium caseinate is useful to prevent the effect of loss of protein and minerals that accompanies the administration of fibers.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have combined the methylcellulose compositions of Dressman with those of Durlach and used the combined composition in a methods comprising the administration of methylcellulose and wheat bran, because Durlach teaches the benefits of using a nutritive fiber such as wheat bran associated with a metallic proteinate for the purpose of counteracting one of the side effects of fiber administration.

### ***Conclusion***

No claim is allowed.



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Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (571) 272-0841.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran

Patent Examiner

June 14, 2004

  
ALANA M. HARRIS, PH.D.

PRIMARY EXAMINER